Chapter-II : Regulatory and Administrative Framework

2.1 Introduction

The Food Safety and Standards Authority of India (FSSAI), under the Ministry of Health and Family Welfare in the Government of India, is responsible for regulating and monitoring food safety in the country, in terms of the Food Safety and Standards Act, 2006, the Food Safety and Standards Rules, 2011 and various regulations on food notified (and amended) since 2011.

2.2 Regulations yet to be framed

Till March 2017, i.e., more than a decade after the enactment of the FSS Act, FSSAI was yet to frame regulations governing various procedures, guidelines and mechanisms on areas covered in different sections of the Act, as below:

- Accreditation of food testing laboratories (Section 16(2)(e)).
- Conducting surveys for enforcement and administration of the Act (Section 16(2)(g)).
- Risk analysis/assessment/communication and management (Section 16(2)(i)).
- Accreditation of food certification bodies engaged in certification of food safety management systems for food businesses (Section 16(2)(c)).
- Organic foods (Section 22)
- Restriction of advertisement and prohibition of unfair trade practices (Section 24).
- Financial Regulations (Section 92(2)(t)).

The Ministry stated (June 2017) that it was not obligatory for FSSAI to make regulations in all cases and it had framed regulations where these were needed the most. The fact remains that FSSAI failed to examine the requirement to frame regulations in respect of aforesaid areas even after a decade of enactment of the Act. This has been discussed in detail in the relevant chapters of this report.

2.3 Failure of FSSAI to regulate Organic Foods

In 2015-16 alone, India produced around 1.35 million metric tonnes (MT) of certified organic products which includes all varieties of food products, and exported organic foods valued at around USD 298 million[1]. Testing centres accredited by the Agricultural and Processed Food Products Export Development Authority (APEDA) certify organic foods manufactured in India. Audit observed that though section 22 of FSS Act stipulates that manufacture, distribution, sale, or import of organic foods is covered under the Act, FSSAI has not framed any regulations regarding organic foods.

The FSSAI and the Ministry accepted the facts (May and June 2017 respectively), but informed that it has now been decided to incorporate the existing National Programme for Organic Production of the Ministry of Commerce and Industry, and the Participatory Guarantee System (PGS) adopted by the Ministry of Agriculture and Farmers' Welfare, and accordingly draft regulations have been framed. The fact, however, remains that no regulations have been notified in respect of organic foods even a decade after the enactment of the Act.

2.4 Deficiencies in the adoption of BIS/AGMARK certifications for specified food products

The Directorate of Marketing and Inspection (DMI) under the Department of Agriculture and Co-operation, Government of India and the Bureau of Indian Standards (BIS) under the Ministry of Consumer Affairs, Food and Public Distribution, Government of India certify agriculture and non-agriculture products respectively[2]. AGMARK and BIS certifications are optional. In terms of FSS regulations[3], AGMARK and BIS certifications are mandatory for 8 and 14 food products respectively.

Audit noted that the FSS regulations have imported all the 22 mandatory certification categories from the erstwhile Prevention of Food Adulteration (PFA) Act, 1954, and the last category under PFA Act was included in June 2009. Audit observed that though perceptions, ingredients, products and processes relating to food safety are continually evolving, and this would necessitate modifications/

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1 Source: Website of Agricultural and Processed Food Products Export Development Authority (APEDA)

2 In terms of the Agricultural Produce Grading and Marking (AGMARK) Act, 1937, and the Bureau of Indian Standards (BIS) Act, 1986 respectively.

3 FSS (Prohibition and Restriction on Sales) Regulations, 2011 and FSS (Packaging and Labelling) Regulations, 2011.

deletions/additions to the certification standards identified under the erstwhile PFA Act, FSSAI has made no efforts to review, for the purpose of possible addition/deletion, the list of mandatory AGMARK and BIS certifications under PFA Act at the time of framing FSS regulations in 2011, or thereafter. Such exercise would also cover areas where the existing BIS/AGMARK certifications are deficient or insufficient.

FSSAI in its reply (May 2017) stated that the industry or consumers have not requested for discontinuation of mandatory certification provisions except the category of blended edible vegetable oils which is mandatorily required to be certified under AGMARK. The Ministry in its reply (June 2017) endorsed the views of FSSAI.

The stand of the Ministry and FSSAI is unacceptable, since the FSSAI is required to independently review mandatory certifications for the purpose of addition/deletion.

2.5 Deficiencies in the formulation of standards

FSSAI formulates standards for various food articles (including their constituents and additives) and processes of manufacture, storage, transportation, sale etc., to ensure availability of safe and wholesome food for human consumption. Audit noticed that though FSSAI has framed standards through regulations, such standards were framed at different periods of time from 2011 onwards, and there is no clarity on the reasons underlying the identification of food products that were standardised, identified ahead of others, and some food products like organic foods (discussed in paragraph 2.3 above) remain to be standardised. Though FSSAI has framed regulations on the working of Scientific Panels and Scientific Committee[4], the areas on which the Panels/Committee deliberate and offer opinion are determined by the executive of FSSAI, and are not based on any defined operating procedure (SOP). There is no clarity on why such areas (and not others) are selected by FSSAI. Further, in some areas, like the framing of regulations on proprietary foods (mentioned in paragraph 2.10(2) below), FSSAI did not involve the Scientific Panels/Committee and the rationale for such exclusions is not clear. FSSAI has also not formulated internal time frames for the processing of standards (apart from the time frames relating to the issue of draft notification and final notification etc.), as a result of which, there were inordinate delays (for instance, the final notification regarding potassium bromate as food

[4] FSSAI (Transaction of Business and Procedure of Scientific Committee and Scientific Panels) Regulations, 2010 (amended in 2016).

additive referred to in the case study below paragraph 2.7.2 was issued five years after identification of risks, mainly because of absence of internal time lines). Ultimately, FSSAI failed to devise action plans to identify areas on which standards are to be formulated/ revisited for revision, if necessary, within specified time frames[5].

The Ministry informed (March 2017) that the identification of areas for examination by the Scientific Panels/Committee and for framing standards is based on scientific evidence. Further, in response to the audit observation, while Ministry had forwarded a statement delineating the process/steps involved in framing regulations, Audit observed that there is no clarity on the first step itself (involving identification of food products on which standards are to be developed/ reviewed), since there is no information on the process through which such identification takes place.

Following the initial audit observation, FSSAI set up eight standards review groups (SRG) in December 2016 to review existing standards applicable to different food categories, and to propose broad new standards; the report of the SRGs would be placed before the concerned Scientific Panels for review and necessary action. However, there is no such provision in the Act to entrust this work to other groups comprised of representatives of FBOs only. This also gives additional credence to the audit observation that identification of areas of examination was not based on scientific process, since there is no evidence on why only eight areas were chosen in the first instance for review of standards. It is also observed that no time frame has been given to the groups for this exercise. Therefore, their opinions/recommendations cannot be considered to be unbiased and beneficial to the interest of food safety affecting the common man.

FSSAI in its reply (May 2017) stated that in the context of revision of standards/formulation of new standards, the Food Authority generally followed a prioritisation approach to address the issues of food safety first. FSSAI further stated that the SRGs are tasked to only suggest areas of new work. Ministry in its reply (June 2017) endorsed the views of FSSAI and stated that this is an internal arrangement for facilitating work and setting up such groups is perfectly in order and desirable in many cases.

The replies are not tenable. There is no evidence to support the FSSAI's contention that it followed a prioritisation approach. The orders on formation of

[5] For instance, the Bureau of Indian Standards has a protocol for revision of standards every five years.

SRGs clearly stated that they were formed for review of existing standards and to propose new standards. Therefore, the concerns of audit on the risks of primarily relying on industry representatives for review of standards, which is the mandate of FSSAI, remain unaddressed.

2.6 Notification without awaiting recommendation of the Scientific Panel/ Committee and without considering stakeholders' comments

Sections 13 and 14 of the Act state that the Scientific Committee assisted by the Scientific Panels provide scientific opinion to the Food Authority. As per section 18(2)(d) of the Act, the FSSAI is required to ensure open and transparent public consultation during the preparation and revision of regulations/standards. Therefore, involvement of the Scientific Panels/Committee and transparent public consultation is inherent to the process of notification of regulations on standards. However, during test check, Audit found a case (discussed below) pertaining to amendment to regulations[6], where the FSSAI bypassed the Scientific Panel/Committee and did not consider the comments of stakeholders before final notification.

Case Study

Stakeholders' comments on the draft notification (February 2015) to include Steviol Glycoside[7] in various food products were placed before the Scientific Panel in its 23rd meeting on 15 October 2015, which directed one of its members to review them for further discussion by the Panel. Without considering the stakeholders' comments or awaiting the review thereon and recommendations of the Scientific Panel, FSSAI notified the final regulation (13 November 2015), without the previous approval of the Ministry as required under section 92 of the Act[8]. Audit further observed that the detailed stakeholders' comments pointed out, *inter-alia*, an error in the draft notification, which did not specify ash content. However, this remained uncorrected in the final notification.

FSSAI/ Ministry in reply (May/June 2017), stated that most of the comments related to inclusion of more food categories in the regulation for use of steviol glycoside. Hence, it was decided to notify the said standards as such without any further delay and that the stakeholders' proposals in respect of addition of more food categories would be covered in the subsequent harmonisation process in

[6] FSS (Food Product Standards and Food Additives) Regulations, 2011.

[7] Chemical compounds responsible for the sweet taste of the leaves of the South American plant Stevia Rebaudiana (Asteraceae), and the main ingredients (or precursors) of many sweeteners marketed under the generic name 'Stevia' and several trade names.

[8] Ministry accorded ex-post facto approval on 25 November 2015.

respect of food additives provisions, which has also been completed since then. Further, the omission of changes in the draft standards was not deliberate but an editorial error.

The replies are not acceptable as there was no record to substantiate that the FSSAI had decided to include more food categories separately. In any event, the notification of regulations without awaiting the opinion of scientific panel was incorrect.

2.7 Delays in notifying amendments to Regulations

Between February 2013 and December 2016, FSSAI notified 43 amendments to three regulations on food standards[9]. During test check of eleven amendments notified up to June 2016 (out of 25 amendment notifications), Audit observed delays in notifying these amendments, which are primarily attributable to lack of policy guidelines and standard operating procedures (SOP). It was noticed that after approval by the Scientific Panels, FSSAI took between 14 to 24 months to notify six amendments, and between 28 to 39 months to notify five amendments. Details are given below:

2.7.1 Delays and deficiencies in referring draft notification to Ministry

Audit observed delays in the following six cases involving amendment to the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, as recounted below:

Case Study 1

After the approval of Food Authority (September 2012) to include 'pullulan'[10] as food additive, the Regulation Division of FSSAI retained the file for 19 months without action, and thereafter referred the file to the Scientific Panel and Scientific Committee for clarifications. The action of the Division to seek clarification on the matter after approval by the Food Authority was inappropriate and inordinately delayed the notification process which was concluded in October 2014.

[9] FSS (Food Product Standards and Food Additives) Regulations, 2011; FSS (Contaminants, Toxins and Residues) Regulations, 2011; and FSS (Packaging and Labelling) Regulations, 2011.

[10] An edible, mostly tasteless polymer, mainly used in various breath freshener or oral hygiene products and as food additive.

Case Study 2

The Scientific Panel recommended (January 2014) five issues to be included in the amendment to the FSS (FPS and FA) Regulation, 2011 for 'salted fish/ dried salted fish'. The Food Authority, however, decided to include only four issues in the amendment, leaving the fifth issue to be covered in a future amendment. At the time of sending the draft notification (August 2014) to Ministry for approval, FSSAI failed to intimate the reason for exclusion of the fifth issue, leading the Ministry to seek clarification (September 2014). Though the decision to exclude the fifth issue had been taken by the Food Authority and not the Scientific Panel (SP) or Scientific Committee (SC), the Regulation Division needlessly referred the matter to the SP and SC (though the decision of the Food Authority was available on the file with the Regulation Division), resulting in five months delay in sending clarification to the Ministry. The draft regulations were notified (June 2015), 17 months after the recommendation of the Scientific Panel.

Case Study 3

FSSAI took more than 19 months, after the recommendations of the Panel (July 2012), to send the file to the Ministry (March 2014) for approval of the draft notification to change the standards for use of different enzymes in bread.

Case Study 4

For amendment to the regulation on revision of standards for blended edible vegetable oil regarding unsaponifiable matter[11] and relaxation or harmonisation of iodine value in imported cotton seed oil with Codex Standards[12], FSSAI took 24 months, after the recommendations (May 2013) of the Expert Group[13], and 19 months after the approval of the Food Authority (January 2014), to send the file to the Ministry for approval of the draft notification. Detailed Audit scrutiny revealed that after approval by the Food Authority (January 2014) certain queries were raised by CEO, FSSAI (May 2014) and it was proposed to discuss these in the Expert Group. However, the matter was not discussed either in the Expert Group or the Scientific Panel which replaced it. It was only after a reminder was received from an FBO (August 2015), did FSSAI realise that the file was unnecessarily pending with them, and sent it to the Ministry (November 2015), without addressing the queries raised by CEO.

[11] Components of an oily (oil, fat, wax) mixture that fail to form soaps when blended with sodium hydroxide (lye) or potassium hydroxide.

[12] A collection of internationally recognised standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety.

[13] Expert Groups on specific matters were replaced by the creation of appropriate Scientific Panels.

Case Study 5

FSSAI took more than 17 months after the recommendations of the Scientific Panel (July 2012), to send the file to the Ministry for approval of the draft notification (January 2014) for amendment to the regulation relating to 'edible common salt'.

Case Study 6

After the Ministry had approved the final regulation (July 2013) on Maximum Residual Limits (MRLs) of antibiotics in honey, FSSAI belatedly realised that prior reference to the World Trade Organisation (WTO) was required, which had not been done. The regulation was finally notified in December 2014, one and a half years after the Ministry's approval.

Though the FSSAI accepted the facts in respect of case studies 1, 3, 5 and 6, it did not respond to the audit observations contained in case studies 2 and 4.

2.7.2 Undue delays in notification of final regulations

The Lok Sabha Committee on Subordinate Legislations had, *inter-alia*, stipulated (December 2011) that the final notification be issued within three months of the last date of receipt of comments/suggestions from stakeholders on the draft notification, if no/less number of comments were received from stakeholders[14]. Audit observed that though only one to two comments of minor nature were received on the draft notifications in four cases, FSSAI took five to ten months for final notification.

The Ministry in their reply (June 2017) endorsed the FSSAI's response (May 2017) that framing regulations is a time consuming process which requires careful assessment of the aspects by different bodies. The replies are not tenable as the committee had limited the period to six months only where many comments were received, which was not the case here. Also, the replies did not address the specific cases pointed out by Audit, where the delays were avoidable.

In the exit conference (June 2017), FSSAI accepted the delays and attributed the delays to the scientific, technical and administrative aspects involved in the process. FSSAI further added that efforts will be made to meet the recommendations of the Lok Sabha Committee on Subordinate Legislation and extensions will be sought wherever required.

[14] Details on the stipulations by the Committee are given in paragraph 2.9 below.

Case Study

Delay in banning Potassium Bromate as Food Additive

FSSAI took nearly five years to ban (June 2016) the use of Potassium Bromate in bread and bakery products after the Scientific Panel recommended (July 2011) its ban on the ground that it was carcinogenic. Audit scrutiny revealed that, for reasons not on record, FSSAI first delayed issuing the draft notification (April 2013) after the belated approval (June 2012) of the Food Authority. Thereafter, for reasons not on record, FSSAI, without informing the Ministry, failed to act on the stakeholders' comments on the draft notification, violating the limit of six months stipulated by the Lok Sabha Committee. However, Potassium Bromate was removed from the list of permitted additives in the regulations[15]notified in September 2016.

Accepting the facts, the Ministry replied (March 2017) that the issue of Potassium Bromate was linked to the work on harmonisation of all the additive provisions with Codex General Standard for Food Additives[16]. The reply is not tenable. There was no evidence on record to support the Ministry's contention that the ban on Potassium Bromate was linked to the harmonisation of the codex (incidentally, the codex had declared Potassium Bromate as a banned item in 2012). It was also observed, that even while the harmonisation exercise was in progress, FSSAI notified other amendments (e.g., the inclusion of pullulan as a food additive). Therefore the notification of standards (including the banning of certain items) is an exercise independent of harmonisation. Finally, and in any case, regulations on the banning of a carcinogenic substance as additive in daily foods should not have been kept pending for five years.

2.8 Product Approval

Between January 2012 and May 2013, the FSSAI issued, without the approval of the Ministry, a series of advisories covering the category of proprietary foods, which have been defined in section 22 of the Act as articles of food for which standards have not been specified but are not unsafe, provided that such food does not contain any of the foods and ingredients prohibited under the Act and regulations made thereunder. These advisories permitted the FSSAI to issue

[15] FSS (Food Products Standards and Food Additives) Amendment Regulations, 2015.

[16] Part of the "Codex Alimentarius" (Food Code), a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission, which is central part of the Joint Food and Agriculture Organisation (FAO) /World Health Organisation (WHO) Food Standards Programme and was established to protect consumer health and promote fair practices in food.

product approvals to individual FBOs for products which were not covered under existing standards.

Audit observed, however, that though the initial advisories required the issue of product approvals to be based on the recommendations of the Scientific Panels, the FSSAI, through subsequent advisories, adopted the issuance of No Objection Certificates (NOC) by the Product Approval division of the FSSAI, for a period of one year, pending recommendation of the Scientific Panels. Such issuance of provisional approvals is not contemplated in the Act, and further, the decision on whether a food product is safe or unsafe (as stipulated in section 22 of the Act) can only be determined by way of scientific opinion, which, only Scientific Panels/ Committee can provide under sections 13 and 14 of the Act.

The last advisory of May 2013 was struck down by the Hon'ble Bombay High Court[17] on 01 August 2014 (and the Hon'ble Supreme Court dismissed the appeal on 19 August 2015) on the ground that the advisories issued by FSSAI without following the procedure laid down under sections 92 (requiring prior approval of the Ministry and previous publication by notification) and 93 of the Act (requiring placing the notified regulations before Parliament) have no force of law. Audit observed, however, that though the FSSAI discontinued the product approval system, it did not take steps to withdraw the licenses issued under the now invalid system, and ensure product recalls. Some of these licenses merited cancellation even under the redundant system, after the FSSAI itself withdrew the NOCs but failed to ensure the cancellation of licenses at that time. Consequently, the possibility that unsafe foods continued to be imported/ produced/ distributed/ sold based on the now invalid licenses cannot be ruled out. Details are given below.

2.8.1 Continuation of licenses issued in terms of flawed NOC procedure

As given in the case studies in the succeeding sub-paragraphs, Audit observed occasions where the NOC issued earlier by the Product Approval division had to be withdrawn because the application for product approval for a similar or identical product was denied by the Scientific Committee/Scientific Panels. It is therefore evident that FSSAI permitted possibly unsafe foods (and foods subsequently determined by the Scientific Panels to be not safe) to be manufactured, distributed, sold or imported in the country. Audit further observed that though the NOCs were valid only for a maximum period of one year, FSSAI did not ensure that the licenses issued on the basis of these NOCs were

[17] Writ Petition No. 2746 of 2013 dated 1 August 2013

accordingly valid for the period of the NOC. Further, after withdrawing the NOCs, FSSAI did not ensure that the Central Licensing Authorities (CLA) also cancelled the licenses that had been issued on the basis of the now withdrawn NOCs and also that the FBOs had stopped the manufacture, distribution and sale of such products.

2.8.2 Continuance/renewal of licenses in violation of Supreme Court orders

In terms of the advisory, the NOCs were valid for a maximum period of one year, Audit, however, observed that after the judgement of the Bombay High Court (01 August 2014) declaring the process of advisories as invalid, FSSAI issued blanket instructions (29 September 2014) to the Central Licensing Authorities (CLA) and directed them to renew/ continue, as required, all existing licenses issued on the basis of NOCs. Consequently, FSSAI permitted the indefinite manufacture, distribution, sale or import of possibly unsafe foods. FSSAI did not take any action after the final orders of the Supreme Court (19 August 2015) to withdraw these blanket instructions. Further, FSSAI failed to withdraw the blanket instructions even after the notification of the amended regulations in respect of proprietary foods (October 2016).

2.8.3 Unauthorised issue of product approvals for proprietary foods by state food authorities

Under the advisory system, only FSSAI had the authority to issue product approvals for proprietary foods on the recommendation of the Scientific Panels. Audit, however, observed that FSSAI did not have any mechanism to ensure that state food authorities did not issue licenses/product approvals on proprietary foods. Test check in Audit revealed that the designated officers in Solan and Sirmaur districts in Himachal Pradesh granted product approvals for a total of 20 proprietary food products during 2014-15, without authority.

2.8.4 Withdrawal of wrongly issued NOCs

2.8.4.1 Issue of NOCs based on recommendations of PA&SC

Under sections 13 and 14 of the Act, only the Scientific Committee/Scientific Panels have been entrusted with the responsibility of providing scientific advice to the Food Authority. Under the product approval system, proposals for product approvals required examination by the Scientific Committee/Scientific Panels. FSSAI constituted a Product Approval and Screening Committee (PA&SC) headed by the Director, Product Approval division to screen the proposals based

on preliminary risk assessment. Audit observed however, that bypassing the requirement for examination by the Scientific Committee/Scientific Panels, the Product Approval division acted on the recommendation of PA&SC and issued NOCs. Moreover, FSSAI had neither framed any Standard Operating Procedures (SOP) to determine the authority competent to approve food products, nor did it delegate such powers to the Product Approval division.

Moreover, the NOCs should have been issued only on the receipt of complete information required for product approval. Audit observed, however, instances where FSSAI issued NOCs even when the product information received was incomplete. In 20 cases (9 *per cent* of the 212 NOCs issued), FSSAI had withdrawn the NOCs issued earlier for reasons including non-furnishing of the complete information by the FBOs. Audit also observed that FSSAI had no mechanism to call for the missing information promptly, and to ensure prompt receipt of wanting information. Illustrative cases are given below:

Case Study 1

FSSAI issued NOC (October 2012) to M/s Art Life Wellness Products for fortified candies (sweets), based on PA&SC recommendation. Thereafter, FSSAI withdrew the NOC (February 2015), due to failure of FBO to furnish the complete details required for submission to the Scientific Panel. Thus, failure of FSSAI to ensure complete documentation before issue of NOC resulted in manufacture and sale of possibly unsafe foods for 28 months between October 2012 and February 2015.

Case Study 2

FSSAI issued NOC (August 2013) to M/s Pushpam Foods and Beverages for four types of energy drinks based on recommendation of PA&SC. However, NOC was withdrawn (November 2014) on the ground that the Scientific Panel had observed (March 2014) in another similar case that the product had an irrational combination of caffeine and ginseng[18], which have opposing effect on the human body. Audit further observed that FSSAI delayed issuing the letter for product recall till May 2015, thereby allowing the FBO a further six months' time to manufacture and sell a product for which NOC had been withdrawn. Overall, the Product Approval division delayed the product recall by 15 months from the date of observation of the Scientific Panel. This resulted in manufacture and sale of

[18] Import of Monster Energy Drink by M/s Narang Danone Access Pvt. Ltd., referred to in paragraph 2.8.4.2 below.

unsafe food products (energy drinks) for 21 months between August 2013 and May 2015.

Case Study 3

Similar to the above case, on recommendation of PA&SC, FSSAI issued NOC (December 2013) to the above FBO (M/s Pushpam Foods and Beverages) for another energy drink, which was withdrawn (June 2015), on the same ground as in the earlier case. Thus, issue of NOC by FSSAI without risk assessment by the Scientific Panel resulted in manufacture and sale of an unsafe food product (energy drink) between December 2013 and June 2015. Audit scrutiny of the website of FBO revealed (April 2017) that the product (Restless caffeinated beverage containing ginseng) continued to be marketed despite the withdrawal of NOC by FSSAI in June 2015.

Case Study 4

FSSAI issued four NOCs (May 2012) to M/s Jagdale Industries for four products (drops, powder, syrup and capsules) sold under the trade name 'Mulmin'. However, the four NOCs were withdrawn (June 2015) after the Scientific Panel did not recommend approval of the products (April 2015). Audit further observed that though the Product Approval division had received all wanting information from the FBO in January 2014, it took 15 months to place the matter before the Scientific Panel, for reasons not on record. Thus, issue of NOC by FSSAI without risk assessment by the Scientific Panel resulted in manufacture and sale of unsafe food products between May 2012 and June 2015. Audit scrutiny of the website of FBO revealed (April 2017) that the unsafe products (drops, powder, syrup and capsules) sold under the trade name 'Mulmin' continued to be marketed despite the withdrawal of NOC by FSSAI in June 2015.

2.8.4.2 Unauthorised and wrong issue of NOC for energy drinks

The FBO, M/s Narang Danone Access Private Limited, applied (December 2012) for product approval for two variations of an energy drink marketed under the trade name "Monster Energy" and intimated that the application for the license would be submitted soon. However, without waiting for FSSAI's product approval, the FBO imported the consignment and intimated (March 2013) FSSAI that 50,632 cases[19] of the product (475 ml. cans) were held up at Nhava Sheva Port, and requested a one-time clearance. The can size exceeded FSSAI's draft

[19] Number of cans per case in this consignment is not known. However canned beverages are normally sold in cases of 24 cans (though, it can range between 12 to 36 cans per case).

standards for caffeinated beverages (250 ml.)[20], which were in the notice of the FBO and were at the final stages of notification (Draft regulations notified on 18 April 2013), and the product (by its nature) could not be repacked in smaller cans even after import. However, for reasons not on record, FSSAI issued permission (April 2013) to transport the product from the wharf area to the FBO's godown. Thereafter, the matter was referred to three different Scientific Panels[21] for examination of various aspects relating to the concerned energy drink. Even while the matter remained under examination with these Scientific Panels, FSSAI issued NOC (October 2013) on the recommendation of the PA&SC. Such issue of NOC on the basis of PA&SC recommendation violated even the FSSAI advisories that did not provide for the PA&SC to review any application that was under examination by the Scientific Panels. Further, FSSAI had no authority to issue NOC on a product that did not meet packaging standards (475 ml. can instead of 250 ml. can). Ultimately, the Scientific Panel on Functional Foods etc., rejected (March 2014) the product, on the ground that it contained irrational combination of caffeine and ginseng, which have opposing effect on the human body. FSSAI withdrew the NOC (September 2014), but the Bombay High Court stayed the matter till May 2015, after which FSSAI once again withdrew the NOC and issued product recall. Audit observed, however, that FSSAI took no steps to ensure that follow up action had been taken on product recall.

2.8.4.3 Non cancellation of licenses of foods declared not safe by Scientific Panel

Audit observed that even after the withdrawal of NOCs, there was no mechanism to ensure that the licenses issued on the basis of the withdrawn NOCs were cancelled. The four cases recounted below relate to withdrawal of NOCs after the Scientific Panels refused product approval. Consequently, unsafe foods continued to be manufactured, distributed, sold and imported despite their rejection by the Scientific Panel, as detailed below:

Case Study 1

FSSAI issued NOC (August 2013) to M/s Surya Herbal Ltd. for Sunova Spirulina Tablets. However, the FBO failed to submit application as required for examination by the Scientific Panel, and NOC was withdrawn (August 2014).

[20] The final notification of 2 December 2016 deleted the reference to per can size limit and only specified that the daily consumption should not exceed 500 ml. per day. Reasons for the deletion by FSSAI are not known.

[21] The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials; the Scientific Panel on Labelling and Claims/ Advertisements; and the Scientific Panel on Functional Foods, Nutraceuticals, Dietetic Products and Other Similar Products.

Audit observed however, that the license of the FBO was not modified/ cancelled accordingly. The Central Licensing Authority (Delhi) informed (August 2016) that they had not received any notice of rejection of the product and the licence issued on the basis of NOC (which has been cancelled) is valid up to December 2017.

Case Study 2

FSSAI issued NOC (July 2012) to M/s. S.K. Industries for two products, based on recommendation of PA&SC. Subsequently, PA&SC reviewed its earlier decision, and FSSAI withdrew the NOC (September 2014). Though the Central Licensing Authority (Delhi) informed that the license of the product had been cancelled, the website of FSSAI continued to show that the license was valid till 01.07.2019. Consequent to the Audit observation in August 2016, FSSAI removed this depiction from its website. Thus, FSSAI took almost two years to remove the food article from the FBO's license after withdrawal of NOC.

Case Study 3

FSSAI issued product approval (January 2013) to M/s. BioCon Ltd. for S-Adenosyl Methionine Tablets. However, in August 2013, product approval was denied to M/s Sun Pharmaceutical Industries Ltd. for the same product. FSSAI failed to resolve this contradiction for more than a year, till it withdrew product approval in the case of BioCon in October 2014. Further, despite withdrawing the product approval to BioCon, FSSAI failed to cancel the corresponding license to BioCon, which continues to be valid upto May 2020.

Case Study 4

FSSAI issued a composite NOC in September 2012 to M/s Hector Beverages for three types of energy drinks. Though FSSAI withdrew the NOC (April 2015) and issued directions for product recall for all three categories (May 2015), the license has not been cancelled till December 2016. The Central Licensing Authority (Delhi) stated (August 2016) that the license was for caffeinated beverages and not for the proprietary products for which NOC had been withdrawn. The reply is not relevant. One specific ground for withdrawal of NOC was the finding of the Scientific Panel that products containing combinations of caffeine and ginseng (as was the case in the three energy drinks under consideration) should not be allowed. Consequently, inaction of FSSAI to cancel the product license resulted in continued sale of an unsafe product more than a year after cancellation of NOC.

2.8.5 Non withdrawal of NOCs

2.8.5.1 Non withdrawal of NOCs despite rejection by Scientific Panel

Test check in Audit of 50 cases (24 *per cent* of the 212 cases where NOCs had been granted by FSSAI) revealed that in four cases, though the Scientific Panel had rejected the food articles, NOCs had not been withdrawn even 31 to 47 months after rejection by the Scientific Panel, resulting in continued manufacture/import and sale of possibly harmful food products. These have been described below.

Case Study 1

FSSAI issued NOC (December 2013) to M/s Pushpam Foods and Beverages for an energy drink which contained caffeine-ginseng combination. Following the vacation of stay by the Bombay High Court (01 May 2015) in the case of another FBO whose product had similar combination of caffeine-ginseng which had been rejected by FSSAI[22], the Chairperson ordered (July 2015) issue of show cause notice to M/s Pushpam also. However, FSSAI failed to issue the show cause notice to the FBO, as a result of which NOC was not withdrawn. (Incidentally, it is observed that FSSAI withdrew NOCs in six other cases based on the same recommendation of the Scientific Panel, without issue of show-cause notice).

Case Study 2

FSSAI issued NOC (August 2012) to M/s Chemical International for a mushroom based nutraceutical. Though the Scientific Panel thereafter rejected (September 2012) the application on the ground of absence of clinical data on immunity benefit claimed by FBO, FSSAI failed to cancel the NOC.

Case Study 3

FSSAI issued NOC (July 2012) to M/s Apex Laboratories for three products (syrup and tablets) with the brand name "Zincovit". Audit observed that though the technical officer in the Product Approval division informed (April 2012) that the syrup contained various ingredients that are not permitted in nutraceuticals, the PA&SC recommended issue of NOC without addressing the concerns on safety and ineligibility of the ingredients used in the syrup. Thereafter, even the Scientific Panel recommended (December 2013) rejection of the products. FSSAI has, however, not cancelled the NOC.

Case Study 4

[22] Import of Monster Energy Drink by M/s Narang Danone Access, referred to in paragraph 2.8.4.2 above.

FSSAI issued NOC (July 2012) to M/s Alkem Laboratories for multivitamin tablets with the brand name "A to Z NS tablets". Though thereafter, the Scientific Panel recommended rejection (December 2013) of the products, FSSAI did not cancel the NOC.

2.8.5.2 No action taken despite failures of FBOs

Audit observed that in the following seven cases (14 *per cent* of the 50 cases referred to above), FSSAI issued NOCs despite failure of FBOs to furnish complete information at the application stage; thereafter, FSSAI delayed in calling the required information; and finally, though the FBOs failed to furnish the information, FSSAI did not take any action against them. Consequently, possibly harmful food products continued to be manufactured/ imported and sold from as early as June 2012. The following case studies illustrate this.

Case Study 1

FSSAI issued seven NOC (April 2013) to M/s Jeevanseva Enterprises for products containing liquid chlorophyll, guarana (a plant containing caffeine), ganoderma (a genus of mushroom), goat's milk candy and ginseng. FSSAI however, wrote to the FBO (September 2014) seventeen months after the issue of NOC, seeking further information from the FBO for submission to the Scientific Panel. Immediately thereafter, the FBO informed (October 2014) FSSAI about the change of its name, but did not furnish any other information. Though the change in name itself warranted immediate change in the status and validity of the NOCs, FSSAI failed to take any action, and there was no change in the status of the seven NOCs.

Case Study 2

FSSAI issued NOC (June 2012) to M/s Sonerge Pharma for New Zealand Royal Jelly (chewable tablets). FSSAI however, took 26 months to process the case for submission to the Scientific Panel, and wrote to the FBO (August 2014) seeking additional information, which has not been provided. FSSAI, however, has failed to take any action against the FBO.

Case Study 3

FSSAI issued NOC (January 2013) to M/s Genext Labs for an energy drink. FSSAI however, took eighteen months to process the case for submission to the Scientific Panel, and wrote to the FBO (July 2015) seeking additional information. However, despite failure of the FBO to furnish information, FSSAI has failed to take any action against the FBO.

Case Study 4

FSSAI issued NOC (September 2014) to M/s ABN Enterprises for a caffeinated energy drink. Though the FBO failed to furnish information sought by FSSAI in September 2014 and July 2015, FSSAI has failed to take any action against the FBO.

Case Study 5

FSSAI issued NOC (January 2013) to M/s Sundyota Numandis Probioceuticals, but took twenty months to process the case for submission to the Scientific Panel, for which purpose, FSSAI wrote to the FBO (September 2014), seeking certain information. However, despite failure of the FBO to furnish information, no action was taken against the FBO.

Case Study 6

FSSAI issued NOC (February 2013) to M/s Red Bull India for the "Red Bull" brand energy drink, but took twenty nine months to process the case for submission to the Scientific Panel, for which purpose FSSAI wrote to the FBO (July 2015) seeking clarifications on certain defects in the application. However, despite failure of the FBO to furnish information, FSSAI failed to take any action against the FBO.

Case Study 7

FSSAI issued NOC (June 2013) to M/s Power Horse India for an energy drink, but failed to submit the case to the concerned Scientific Panel at any time. In the meantime, FSSAI itself found certain deficiencies in the application and sought clarifications from the FBO (July 2015). However, despite failure of the FBO to furnish information, no action was taken against the FBO.

The Ministry replied (March 2017) that FSSAI had decided not to issue product approvals and NOCs in 2,094 cases where information/documents were not furnished by FBOs. The reply is not relevant, since it does not address the issue of delay by FSSAI (for more than one year and for almost three years) to process the applications for examination by the Scientific Panel, and FSSAI's further failure to take action against the FBOs who had failed to furnish information.

2.8.6 NOC cases not submitted to Scientific Panels despite specific PA&SC recommendation

Though the PA&SC issued 212 NOCs, FSSAI failed to confirm to Audit on the number of cases out of these 212 cases which were referred to Scientific Panel.

Audit observed, however, that though, in 27 out of 50 cases test checked (54 *per cent*), the PA&SC had recommended referring the cases to the Scientific Panels for examination and appropriate decision, FSSAI failed to do so, and without recording any reasons, issued NOCs (October 2012 to January 2015) in all these cases.

In response to the Audit observations contained in paragraph 2.8 (and sub-paragraphs thereunder), the Ministry reiterated (June 2017) the reply of the FSSAI (May 2017) that the issue pertaining to the erstwhile product approval system appeared to be redundant in view of its withdrawal upon the directions of the Hon'ble Bombay High Court and Supreme Court. The Ministry/ FSSAI further stated that the Food Authority has approved new regulations concerning approval of non-specified foods and ingredients in May 2017 and all old cases could be resolved once these are notified.

The replies are not acceptable, since they have not addressed the primary audit concern that the FSSAI had failed to ensure the cancellation of the licenses issued under the product approval system declared unlawful by the Supreme Court, and order product recalls, resulting in possibly unsafe food continuing to be imported/ manufactured/distributed/sold in the country. The response that the issue was now redundant cannot be used to brush away the serious defects in the functioning of the product approval system, which reflects poorly on the systemic functioning of the FSSAI itself.

2.9 Wrongful operationalisation of Regulations under Section 16(5)

In terms of the judgements of the Bombay High Court and the Supreme Court (referred to in paragraph 2.8 above), the powers exercised by Food Authority under sections 16(1) and 16(5)[23], the general principles of food safety enshrined in section 18, and the specific provisions relating to proprietary foods etc., in section 22, shall be subject to the overarching provisions of sections 92 and 93 of the Act. Section 92 stipulates, *inter-alia*, that the Food Authority may (a) with the previous approval of the Central Government and (b) after previous publication, (c) by notification, make regulations under the Act. Section 93 requires all rules and regulations to be laid, after they are made, before each house of Parliament.

[23] Section 16(1) states the duties of the Food Authority. Section 16(5) empowers the Food Authority to give binding directions to the Commissioners of Food Safety (*viz*., the CEO, FSSAI in respect of the Centre, and the Commissioner nominated by the concerned State government).

The report of the Committee on Subordinate Legislation[24] has stipulated that, before complying with the requirement of 'previous publication' under an Act, the following procedure was to be followed, *viz.,* the framing of draft rules in consultation with Ministry of Law and Justice, their publication in the official gazette inviting objections and suggestions within thirty days, obtaining suggestions from interested groups, considering the objections/views, finally notifying the rules (in consultation with Ministry of Law and Justice) within six months of last date of receipt of comments (if number of responses are large) and within three months (if number of responses are small or nil).

Audit noticed many instances where, contrary to the above requirements, FSSAI issued directions under section 16(5) without adhering to the requirements of sections 92 and 93 of the Act. FSSAI, by these directions, wrongly operationalised the codex standards for various commodities, prescribed the permissible limits of iron filings in tea, removed zinc from the list of contaminants, and introduced a new category for unprocessed whole raw pulses with reduced standards. Details are given below.

2.9.1 Directions issued by-passing open and transparent public consultation

Case Study

FSSAI operationalised (April 2016) Codex Standards for various commodities by exercising its powers under section 16(5), by-passing the process of open and transparent public consultation (mandated under section 18(2)(d) of the Act), without the prior approval of the Central Government and previous publication by notification (mandated under section 92 of the Act) or the Food Authority.

2.9.2 Directions issued without progressing beyond stage of issue of draft notification

Case Study 1

FSSAI had issued three advisories (May 2014, November 2014, and May 2015) prescribing the permissible limit of iron filings in tea. Though these advisories became invalid from 19 August 2015 (the date of the Supreme Court judgement), FSSAI, contrary to the judgement, allowed the third advisory to continue till 21 November 2015, its normal expiry date. Thereafter, FSSAI issued a draft notification on 04 December 2015, followed by a revised draft notification of 17 May 2016. On 22 April 2016 (i.e., prior to the issue of the second draft

[24] 15th Lok Sabha (2011-12) dated 16 December 2011.

notification), FSSAI, without the approval of the Food Authority or the Ministry, issued directions under section 16(5) of the Act implementing the draft standard that prescribed the limit of not more than 150 mg/ kg of iron filings in tea. The regulation was finally notified on 29 December 2016, eight months after the unauthorised operationalisation. The operationalisation of standards under section 16(5) without completing the procedure delineated under section 92 and 93 amounted to violation of the Act.

Case Study 2

FSSAI issued the draft notification for 11,000 food additives on 04 August 2015. On 20 June 2016, without issuing the final notification, and without the approval of the Food Authority or the Ministry, and violating the Supreme Court judgement, FSSAI issued directions under section 16(5), and operationalised the standards. The regulations were finally notified on 05 September 2016.

Case Study 3

FSSAI issued the draft notification (April 2016) for removal of zinc from the list of contaminants. However, FSSAI issued directions under section 16(5) of the Act, and implemented the regulation with effect from 02 May 2016 before notifying the final regulations. Such use of section 16(5) without following the provisions of section 92 violated the Act. The regulations were finally notified on 10 October 2016.

Case Study 4

FSSAI issued draft notification (28 April 2016) to create a new category: "unprocessed whole raw pulses (not for direct human consumption)" containing reduced standards on permissible limit of foreign (extraneous) matter otherwise applicable to the general raw pulses category. The final regulation was notified on 14 September 2016. Audit observed that, even prior to the issue of the draft notification, FSSAI issued directions (13 April 2016) under section 16(5) implementing the proposed regulation with immediate effect in violation of the Act.

2.9.3 Extension of date of implementation of regulations without amendment notification

In the following two cases, without following the process mandated under section 92 of the Act, and in violation of the Supreme Court judgement, FSSAI wrongly exercised section 16(5) to extend the date of implementation specified in the gazette notification.

Case Study 1

The gazette notification (May 2016) amending the regulations on labelling of pre-packaged foods in the category of edible vegetable oil/ fat, stipulated that the amendment came into effect on 25 May 2016. FSSAI, however, on 30 July 2016, invoked section 16(5) and extended the date of effect to 02 December 2016, bypassing the requirement of amendment to the earlier regulation through gazette notification.

Case Study 2

The gazette notification dated 04 August 2016 amending the regulations on margarine and fat spreads was to become effective from 27 August 2016. On 10 August 2016, FSSAI wrongly exercised section 16(5) of the Act, and extended the date of effect to 27 February 2017, bypassing the requirement of amendment through gazette notification.

The Ministry accepted (June 2017) the Audit contention that the date of implementation of a regulation notified in the official gazette with the approval of the Central Government should not be modified except by way of amendment in the said regulation through a gazette notification with the approval of the Central Government.

As recounted in the seven case studies above, FSSAI violated the Act and also Supreme Court judgement by taking recourse to section 16(5) of the Act to operationalise regulations without completing the procedure stipulated in section 92 of the Act.

Replying to the Audit observations, the Ministry stated (January 2017 and March 2017) that the judicial pronouncement was only with reference to a particular case relating to nutraceuticals and had no bearing on the powers conferred on FSSAI under section 16(5) of the Act to issue binding directions to the Commissioners. The Ministry also stated that these directions were issued to operationalise the standards on interim basis so that FBOs can use the standards, and based on their feedback, the standards can be revised at the time of final notification. The

Ministry further stated that the exercise of section 16(5) was legitimate and became inevitable after the product approval system was discontinued and earlier approved products could not be regulated and new proposals could not be entertained.

The replies of the Ministry are not acceptable. Though the writ petition in the case was initially heard by a two member Bench of the Bombay High Court on a limited issue, due to a difference of opinion between the two learned judges, they referred the matter to the Chief Justice of the High Court to frame the matter on the fundamental issue of whether FSSAI is empowered to apply other provisions of the Act, including section 16(5), without following the procedures contained in sections 92 and 93 of the Act. In these circumstances, once the three member bench of the High Court constituted by the Chief Justice decided (on which the Supreme Court also refused to intervene) that all the other sections are subordinate to sections 92 and 93 of the Act, the contentions of the Ministry regarding the interim instructions issued under section 16(5) are also untenable. The Ministry should have sought the opinion of the Ministry of Law, rather than attempting an interpretation of the scope of the orders of the Bombay High Court and the Supreme Court judgement.

FSSAI in its further reply (May 2017), stated that if the Ministry agrees, opinion of the Law Ministry will be sought.

2.10 Deficiencies in the amendment to regulations relating to proprietary foods

In the aftermath of Hon'ble Bombay High Court and Hon'ble Supreme Court judgements in August 2014 and August 2015 respectively, FSSAI discontinued the product approval system in August 2015. Thereafter FSSAI initiated the process for notifying regulations to regulate proprietary foods. The process began with notification of interim regulations on proprietary foods on 12 January 2016 and culminated on 10 October 2016 with notification of Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016 for proprietary foods.

Audit noted the following deficiencies in the process underlying the final notification for proprietary foods:

(1) To ensure open and transparent public consultation in terms of the procedure delineated under section 92 of the Act and by the Lok Sabha

Committee on Subordinate Legislations, all regulations are required to follow a detailed consultative process with stakeholders. However, section 18(2)(d) of the Act contains an exception, permitting the Food Authority to dispense with such consultation in the making or amendment of regulations, where it is of the opinion that there is an urgency concerning food safety or public health. Such exception is, however, subject to the condition that such regulations shall remain in force for not more than six months. Audit noted that on 11 December 2015, the Ministry issued directions under section 85 of the Act (empowering the Ministry to, *inter-alia*, issue directions to FSSAI) stating that to cover the time required to frame regulations in place of the existing advisories, FSSAI may operate the urgency clause, i.e. section 18(2)(d), and issue regulations without public consultation, for a period not exceeding three months. Though the interim regulations on proprietary foods were accordingly notified on 12 January 2016, FSSAI failed to notify the final regulations within the time stipulated by the Ministry, and therefore, the interim regulations ceased to be in force after 11 April 2016. To overcome this failure to notify the final regulations in time, FSSAI wrongly exercised (22 August 2016) the provisions of section 16(5) to operationalise draft regulations issued on 19 April 2016. In the absence of underlying regulations under section 92, operationalisation of the regulations under section 16(5) was a violation of the Act, which gets further substantiated in the light of the orders of the Bombay High Court and the Supreme Court. Audit observed that between 11 April 2016 (date of cessation of interim regulations) and 21 August 2016 (date of invoking of section 16(5)), FSSAI had issued 118 licenses and between 22 August 2016 and 10 October 2016 (date of notification of final regulations), FSSAI had issued 20 licenses.

The Ministry replied (March 2017) that consequent to the orders of the Supreme Court it was no longer possible to continue the process of product approvals and issuing of advisories. Hence, several food products, both domestic and imported, for which product approval was sought from FSSAI before the Supreme Court's orders were left in limbo. Further, no new proposals from the industry could be entertained any more. Therefore, it was necessary to implement these standards with immediate effect to address the issues of food safety and to regulate the non-standardised food products, which constitute a major portion of product approvals.

The reply is unacceptable as FSSAI and Ministry invoked the urgency provisions of 18(2)(d) on 12 January 2016, i.e., more than four months after the Supreme Court orders. Further FSSAI/ Ministry took nine months after the invoking of

section 18(2)(d) and more than thirteen months after the Supreme Court orders to notify the final regulations on 10 October 2016. The reasons for FSSAI's inability to adhere to these time lines have also not been explained by the Ministry.

(2) In terms of the framework (stated by FSSAI to be followed by them), all matters regarding standards are required to be first referred to the Scientific Panels and the Scientific Committee. Audit observed, however, that the regulations on proprietary foods notified on 10 October 2016 were not referred to the Scientific Panels and Scientific Committee at any stage.

The Ministry replied (March 2017) that the original regulations of 2011 had defined proprietary foods. In view of the generality of this definition, which provides an explanation about the ingredients including food additives that can be used in proprietary foods and various other requirements pertaining to microbiological quality, labelling, etc., no technical inputs from the Scientific Panels and Scientific Committee were required.

The reply is not acceptable as the Ministry's reply does not include any evidence that a conscious decision was taken by the competent authority to dispense with referral to Scientific Panel and Scientific Committee in this case. Further, as explained in the sub-paragraph below, the final regulation of 2016 has deviated from the definition of propriety foods and novel foods as defined in the Act and contained in the original regulations of 2011. For this reason at least, the regulations should have been referred to the Scientific Panels and Scientific Committee.

(3) Section 22 of the Act defines proprietary foods and novel foods similarly (treating them same), as articles of food for which standards have not been specified but are not unsafe or contain any of the foods and ingredients prohibited under the Act and regulations made thereunder. This definition was followed in the original (amendment) regulations of 2011. Audit observed, however, that the amended regulation of 2016 defined proprietary foods as excluding novel foods.

Admitting the difference in the definition between the Act and the regulations of 2016, Ministry replied (March 2017) that this was mainly done for facilitating innovations by the industry and for protection of consumer's interest. Though the Act provides for the same definition for the proprietary food and novel food, technically, novel foods are those foods which contain ingredients and additives which do not have any history of use in the particular region/country; or the foods

which are manufactured using a new technology other than conventional technology.

The reply of the Ministry is not acceptable. No regulation can contain a definition different from the underlying Act. The Ministry was therefore required to either amend the definition in the regulations so that it was in consonance with the Act or take measures to amend the Act itself.

(4) Audit also observed that the amended regulations merely state that individual ingredients should conform to the standards prescribed by FSSAI (or in the case of micronutrients, i.e., vitamins and minerals, the limits of recommended daily average)[25], without mentioning which combinations of ingredients (though individually meeting the standards), would violate the overall stipulation of food safety. For instance, the Scientific Panel had rejected (in January 2014 and March 2014) caffeine-ginseng combinations in energy drinks on the ground that it may have opposing effect on the human body (discussed in case studies 2 and 3 below paragraph 2.8.4.1, paragraph 2.8.4.2, case study 4 below paragraph 2.8.4.3 and case study 1 below paragraph 2.8.5.1).

FSSAI stated (May 2017) that it would holistically look into the issue of combinatorial effect of ingredients including that of caffeine and ginseng in the near future based on the international best practices.

The Ministry (June 2017) agreed with Audit that the Ministry's approval should be taken before operationalising/notifying any regulations.

2.11 Deficiencies in operationalisation of Import Regulations

FSSAI notified the draft Food Safety and Standards (Food Import) Regulation on 17 May 2013, but failed to finalise it. In the interim, FSSAI issued various advisories on imports, which became invalid in light of the Supreme Court decision of 19 August 2015. Despite this, decisions continued to be taken on the basis of the invalid advisories.

On 14 January 2016, citing the urgency clause contained in section 18(2)(d) of the Act, FSSAI operationalised a revised draft regulation and placed it on its website. This action of FSSAI violated the Act as Section 92(2)(g) of the Act stipulates that the exercise of section 18(2)(d) requires the previous approval of the Central

[25] Though the Scientific Committee/Scientific Panels of FSSAI cite the RDA limits for micronutrients prescribed by the Indian Council of Medical Research (ICMR), this authority has not been mentioned by FSSAI in the regulations.

Government. In this case, since the earlier draft notification was superseded by the revised draft notification which was approved by the Ministry only on 15 July 2016[26], the condition of previous approval of the Central Government were not met. Despite this, the Ministry accorded *ex-post facto* approval (15 July 2016) for invoking section 18(2)(d).

In keeping with the time limit of six months stipulated in section 18(2)(d) of the Act relating to the urgency clause, the Ministry exercised its powers under section 85 of the Act, and limited the period to three months[27]. Therefore, even had the regulations of 14 January 2016 been valid, they remained in force only till 13 April 2016. Since FSSAI did not notify the final regulations before this date, the invalid regulations also lapsed within three months of issue. FSSAI finally issued fresh directions on 02 September 2016 and operationalised the draft revised regulations invoking section 18(2)(d) read with section 16(5) of the Act. Since FSSAI was under the mistaken impression that the earlier operationalisation remained in force for six months, it retrospectively operationalised the regulations from 15 July 2016. The second operationalisation suffered from the same defects as the first operationalisation, in that, it was issued without previous approval of the Central Government. In addition, the simultaneous exercise of sections 16(5) and 18(2)(d) is contradictory, since the former section relates to the exclusive powers of FSSAI to ensure furtherance of the Act, Regulations and Rules, and the latter section relates to the exclusive power of the Ministry to give previous approval. In any case, FSSAI had no authority to invoke section 16(5) in this case, since the situation of FSSAI necessitating the issue of regulations to replace the earlier advisories arose only after the Bombay High Court and Supreme Court had decided that the powers of FSSAI under section 16(5) could not override the provisions of sections 92 and 93 of the Act. Further, neither FSSAI nor the Ministry have the power to extend the maximum period of six months provided under the exception clause in section 18(2)(d) of the Act. In any case, FSSAI did not refer the second operationalisation to the Ministry for approval at any stage. And finally, the Act does not provide for any retrospective effect to regulations.

As in the case of the first operationalisation, FSSAI was under the mistaken impression that the second operationalisation remained in force till 14 January 2017. Accordingly, and since the revised draft notification (issued on 25 October 2016) was still under process for being notified as regulations, FSSAI, in

[26] The revised draft regulation was notified on 25 October 2016.

[27] Ministry of Health and Family Welfare Directions No. P15025/250/2015 (1)-DFQC dated 11 December 2015.

continuance of its earlier unauthorised and incorrect actions, operationalised the regulation for the third time, with effect from 14 January 2017. The final regulations were notified on 09 March 2017.

In their reply (March 2017), the Ministry has tried to justify the use of section 18(2)(d) by stating that this was inevitable once the existing advisories on imports became redundant following the Supreme Court decision. The reply is not acceptable, since, the Ministry was not even aware of the fact that FSSAI had exercised the exception clause under section 18(2)(d) on the second and third occasion. Further, the exercise of the exception clause under section 18(2)(d) without the previous approval of the Ministry on all three occasions cannot be justified, as also, the extensions beyond 14 July 2016 (the maximum period of six months) contrary to the Act.

FSSAI stated (May 2017) that it was not under a mistaken impression that the operationalisation remained in force for six months, since this is specifically mentioned in the Act. FSSAI has also contended that section 18(2)(d) does not mention that the urgency clause should be invoked only once for a regulation. The Ministry, however, stated (June 2017) that the approval of the Ministry should be taken before operationalising any regulations. The Ministry's views conform to the Audit contention.

2.12 Food borne diseases

Section 35 of the Act states that the Food Authority may, by notification, require registered medical practitioners carrying on their profession in any local area specified in the notification, to report all occurrences of food poisoning coming to their notice to such officer as may be specified. Audit, however, noted that no such notification was ever issued/ published by the Food Authority.

The Ministry, while accepting the Audit observation, replied (March 2017) that the Food Authority was in the process of issuing the notification.

2.13 Non-preparation of General Plan for Crisis Management

Sub-section (3)(d) of Section 16 of the Act states that the Food Authority shall provide scientific and technical advice and assistance to the Central Government and the State Governments in implementation of crisis management procedures with regard to food safety and to draw up a general plan for crisis management and work in close co-operation with the crisis unit set up by the Central

Government in this regard. Audit noted that FSSAI has initiated no mechanism to provide technical advice to the Central and State Governments.

The Ministry in its reply (June 2017) accepted the facts.

2.14 State/District Advisory Committees

As per Section 2.1.15 of Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011 and directives (July 2012) of the Central Advisory Committee of FSSAI, a State Level Steering Committee (SLSC) or State Advisory committee (SAC), with Chief Secretary as its Chairperson, and District Level Steering Committee (DLSC) or District Advisory Committee (DAC) with District Collector as its Chairperson be constituted to assist, aid or advise on any matter concerning food safety in the State. Decisions taken at the monthly meetings of these committees are to be forwarded to appropriate authority for action.

Audit test check in ten States revealed that SACs had not been constituted in Odisha and West Bengal. In Delhi, Haryana, Himachal Pradesh and Tamil Nadu, the SACs did not hold any meetings. In Assam, Gujarat, Uttar Pradesh, the SACs met only once during the entire audit period and in Maharashtra it met twice.

No DACs had been constituted in the test checked districts in Odisha, Delhi and Haryana. Only one of the six districts test checked in Maharashtra, three of the five districts test checked in Tamil Nadu, seven of the ten districts test checked in Uttar Pradesh, and one of five districts test checked in West Bengal had DACs. Even after the Central Advisory Committee issued directives (July 2012) to hold regular meetings, till date (March 2016), in the five test checked districts of Assam, no meetings were held in four districts and only two meetings were held in one district; in Maharashtra, out of six test checked districts, five districts did not have committees and in the sixth district, five meetings were held; in Tamil Nadu, out of six test checked districts, the committees did not hold any meeting in two districts, two meetings were held in one district and one meeting each in the remaining three districts; in Uttar Pradesh, out of ten test checked districts, no committees have been constituted in three districts; out of the remaining seven districts, the committees did not hold any meeting in five districts, ten meetings were held in one district and only one meeting in the last district; in West Bengal, out of five test checked districts, no committees have been formed in four district and in one district, three meetings have been held; in Gujarat and Himachal

Pradesh, no meetings were held during the entire audit period by any of the test checked DACs.

While accepting the Audit observation, the Ministry replied (January and March 2017) that the issue of holding regular meetings of SAC and DAC had been the point of discussion in various meetings of the CAC and instructions had been reiterated to Food Safety Commissioners to ensure this. The fact, however, remains that the requirements regarding the constitution/regular meetings of SAC and DAC are yet to be fully complied with.

2.15 Management of internally generated funds

2.15.1 Funds lying unutilized

As per rule 209(6)(xiv) of the GFR, 2005, the grant sanctioning authorities should take into account the internally generated resources while regulating award of grants.

Audit observed that FSSAI had collected ₹ 100.73 crore by way of license fee, testing and laboratory fee etc., since 2008 onwards, which remained unutilised. FSSAI did not frame regulations for utilisation of these funds.

FSSAI in its reply (March 2017) stated that financial regulations/ guidelines in this regard are being formulated.

2.15.2 Non refund of product approval fee

Audit observed that though 1,876 applications for product approval were pending with FSSAI after the Supreme Court judgement (19 August 2015), FSSAI has not refunded ₹ 4.69 crore (at ₹ 25,000 per application) to the applicants. In their reply (January, March and May 2017), FSSAI/Ministry stated that FSSAI had decided that where tangible action had been taken on applications, fees need not be refunded and all pending applications would be processed based on existing regulations and new regulations as and when notified. Ministry has defined "tangible action" as the process of screening, examining, processing, segregation and recommending for issue of license in accordance with new regulations. It contended that the application fee may not be considered for the purpose of issuing NOC/product approval alone but also for taking action on the application. The reply is not tenable. In the aftermath of the Supreme Court decision, FSSAI has no authority to issue any more NOC/product approvals and therefore has no

reason for considering such applications. Ministry may consider approaching Ministry of Finance for clarity on the issue.

In the exit conference (June 2017), FSSAI/Ministry stated that the fee cannot be refunded, however, under the new regulations being framed in-lieu-of product approval system, no fees will be charged from such applicants.

2.16 Insufficient Information, Education and Communication (IEC) activities by States

The Central Advisory Committee (CAC) in its 8th meeting (July 2012) advised that at least 75 *per cent* of the food license fee collections (₹ 302.85 crore during the audit period) be used for IEC activities. Test check in the ten selected states revealed that this was not done. Further, none of the state governments had framed any policy for IEC activities. Only two states (Assam and Tamil Nadu) had allocated budget for IEC activities, while the other states (Odisha, Himachal Pradesh, Gujarat, West Bengal, Uttar Pradesh, Haryana and Delhi[28]) did not allocate any budget for IEC activities.

The Ministry (March and June 2017) stated that it had been repeatedly reminding the State Governments to take necessary measures for implementation of the above cited advisory of CAC. The fact remains that the advisory of the CAC is yet to be complied with.

2.17 Use of advertising by FBO on FSSAI publications

FSSAI published two booklets[29] for the elucidation of safe food practices to the general public. Audit, however, observed that two leading FBOs advertised on the back page of the publications. Such practices would lead the public to believe that the FBOs had the official sanction of the FSSAI in its capacity of food regulator, which is not desirable, and adversely impacts the FSSAI's role as an independent regulator.

FSSAI in its reply (May 2017) stated that, these activities were carried out by FBOs under CSR (Corporate Social Responsibility) in public interest as these documents have been made available as open source inputs in the public domain through the FSSAI website and other portals. For greater clarity, a policy on use of CSR and other voluntary initiatives to be taken up in public interest has now

[28] Information regarding Maharashtra is not available.

[29] (i) DART- Detect adulteration with Rapid Test and (ii) The Pink Book- Your guide for safe and nutritious food at home.

been approved by the Food Authority in its meeting held on 25 May 2017. The Ministry (June 2017) reiterated the stance of FSSAI. The reply, however, does not address the specific concerns of Audit. The Ministry is required to frame guidelines to ensure that the role of FSSAI as an independent regulator is not compromised.

2.18 Defects and deficiencies in grievance redressal

FSSAI primarily handles complaints received through the Centralised Public Grievance Redress and Monitoring System (CPGRAMS) of Department of Administrative Reforms and Public Grievances (DARPG), letters from complainants, various Ministries, faxes and its own web portal. FSSAI, however, has not framed any standard operating procedure (SOP) on handling, redressal, and disposal of complaints. Audit scrutiny also revealed that there was no mechanism to redress the grievance and respond to the complainant.

Audit further observed that out of the 163 complaint cases received at the FSSAI during August 2011 to March 2016 pertaining to eight states (Delhi, Gujarat, Haryana, Himachal Pradesh, Maharashtra, Odisha, Tamil Nadu and Uttar Pradesh), 11 cases were not forwarded to the respective State Food Commissioners, while in the remaining cases the State Food Safety Commissioners had not responded. The state food authority, Delhi could furnish Audit with documentary proof of redressal only in respect of ten out of the 58 cases referred to it by the FSSAI. Three states (Odisha, Himachal Pradesh, and Tamil Nadu) did not have a Grievance Redressal Mechanism. In five States (Assam, Delhi, Haryana, Gujarat and Uttar Pradesh), the system was not effective.

The FSSAI/Ministry (May/June 2017) accepted the audit observation.

Conclusion:

Even after more than a decade of the enactment of the Act, FSSAI is yet to frame regulations governing various procedures, guidelines and mechanisms enunciated in different sections of the Act. FSSAI failed to devise action plans to identify areas on which standards are to be formulated/revisited for revision within specified time frames, and the manner of selection of food products for formulation of standards. FSSAI did not involve the Scientific Panels/Scientific Committee in the formulation of standards of certain foods. FSSAI notified regulations and standards without considering the comments of stakeholders. In absence of standard operating procedures (SOP), FSSAI took between one year

and three years to notify amendments. Possibility of unsafe/declared unsafe foods continued to be manufactured and sold could not be ruled out due to failure of FSSAI to monitor and cancel licenses issued under flawed procedure for NOC, even subsequent to the Supreme Court declaring the entire procedure of issuing advisories on NOC and product approvals as unlawful. FSSAI continues to issue directions under section 16(5) of the Act without following the procedure underlying sections 92 and 93 of the Act, despite the orders of the Supreme Court that such orders do not have the force of law. FSSAI has not yet issued notifications requiring registered medical practitioners to report all occurrences of food poisoning in their jurisdiction. FSSAI has not drawn up a general plan for food crisis management and introduced a mechanism to ensure its implementation. FSSAI has not ensured that all states have constituted State and District Advisory Committees, and that these are functioning effectively. FSSAI did not frame regulations for utilisation of funds of ₹ 100.73 crore it had collected since 2008 by way of license fee, testing and laboratory fee etc., which remained unutilised. Despite recommendation of the Central Advisory Committee (CAC) that at least 75 *per cent* of the food license fee collections are used for Information, Education and Communication (IEC) activities, most states had not allocated any budgets for these activities.

Recommendations:

- *Ministry/FSSAI may expedite the notification of regulations on areas that have been specified in the Act, but are yet uncovered.*
- *FSSAI may frame standard operating procedures on the formulation and review of standards and ensure that these are adhered to.*
- *FSSAI may ensure that all licenses issued under the erstwhile system of product approvals are reviewed, and licenses cancelled and reissued as warranted under the present procedure.*
- *FSSAI may review all directions issued under section 16(5) of the Act in the light of directions of the Hon'ble Bombay High Court and Hon'ble Supreme Court.*
- *FSSAI may expedite the notification of financial regulations for utilisation of funds collected by way of license fee, testing and laboratory fee etc., collected since 2008 onwards.*